UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	Hon. Patti B. Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc. CIVIL ACTION NO. 06-11337-PBS	Magistrate Judge Marianne B. Bowler

UNITED STATES' OBJECTIONS TO JULY 19, 2007 ORDER BY MAGISTRATE JUDGE BOWLER

Pursuant to Fed. R. Civ. P. 72(a) and Rule 2(b) of the Rules for the United States Magistrates in the United States District Court for the District of Massachusetts, the United States of America, through its undersigned counsel, respectfully files it Objections to the July 19, 2007 Order by Magistrate Judge Bowler (the "Order") on (1) Third-party TAP Pharmaceutical Products Inc.'s Motion for a Protective Order and Motion to Quash Plaintiffs' Third Party Subpoenas (Docket Entry # 4295); (2) Third-party Hospira, Inc.'s Motion for a Protective Order and Motion to Quash Plaintiffs' Third Party Subpoenas (Docket Entry # 4294); and (3) Defendant Abbott Laboratories Inc.'s Motion for Protective Order and Motion to Quash Plaintiffs' Third Party Subpoenas (Docket Entry # 4296) (jointly referred to as the "Motions to Quash"), and states:

I. PRELIMINARY STATEMENT

The Order rigidly limits the scope of the United States' discovery in this matter. First, the United States has been barred from getting *any* discovery prior to 1991 or after 2003. There are instances where evidence, such as evidence related to the launch of a drug that is identified in

this suit, pre-dates 1991 and should be discoverable. Similarly, there may be evidence of subsequent remedial actions that post-date the implementation of the Medicare Modernization Act in 2004 that should be discoverable. The United States respectfully submits that there should not be a firm temporal limit to discovery in this matter. Abbott has no legitimate objection to this amendment to the ruling since it is seeking testimony from witnesses who left the Government in the 1980s and for documents related to reports issued between 1968 and 2007, well outside the temporal scope discovery limitations placed on the United States.

Second, this Court has recognized that there are cross-cutting issues that will require discovery beyond documents and testimony related to the drugs identified in the United States' Complaint and beyond the divisions of Abbott that manufactured and sold those drugs. The Order too narrowly defines the circumstances in which the United States should be permitted to obtain discovery on issues or drugs that go beyond the drugs identified in its Complaint. As discussed below, it is critically important for the United States to be able to assemble evidence of intent and knowledge by showing Abbott engaged in a pattern and practice of similar wrongful conduct in other analogous circumstances in connection with other drugs and other divisions or affiliates of the company. It is also critically important for the United States to be able to compare Abbott's conduct on other drugs and in other time frames to the conduct upon which the damages are based, as a method of proving that AWP-based drug reimbursement drove Abbott's conduct.

II. OBJECTIONS

The United States objects to the Order of Magistrate Bowler (attached as Exhibit A) in the following respects:

1. The Order may be read to have quashed the United States' third party subpoenas in their entirety, rather than having narrowed the

subpoenas consistent with the Order.[1]

2. The Order granted in part the motions to quash based on burden, yet the subpoena recipients had not sought relief on that basis (or on any basis).[2] Further, none of the moving parties – Abbott and Abbott-related entities – demonstrated any burden or the appropriateness of a relevance limitation.

3. The operative language of the Order implemented the prior guidance from this Court too restrictively. The Order concluded that the subpoenas, "which seek discovery from January 1990 to the present and extend to drugs not charged in the complaint" are intrinsically over broad and burdensome. The Order also concluded that the "relevance of documents created after 2003, even corrective documents regarding the marketing of the spread and the setting of the average wholesale price ("AWP"), is also *highly questionable"* (emphasis added). The Order further limited discovery related to "any alleged effort on the part of Abbott to market the spread or manipulate the published AWP for any drug" to the drugs "within Abbott's former hospital products division." Finally, the Order limited discovery to the drugs identified in the United States' Complaint, except in narrow circumstances.

III. REQUESTED RELIEF

The United States requests that discovery proceed as follows:

1. That the Court clarify that the United States' subpoenas to third-parties are not quashed, but that Abbott's, Hospira's and TAP's Motions for Protective Orders are granted in part, if at all, consistent with this Court's ruling on the appropriate parameters of discovery.

2. The United States should be provided discovery sufficient to understand how Abbott priced and marketed drugs other than those identified in the Amended Complaint so as to develop pattern and practice evidence. This

---

[1] Magistrate Bowler granted in part and denied in part the Abbott, TAP and Hospira motions to quash, stating that "the present third party subpoenas are . . . quashed", but directing the United States to "to narrow the subpoenas consistent with this Order." The Order went on to say that, "[T]he motions are denied, however, with respect to documents already produced or documents to which the recipients have agreed to produce in the future notwithstanding the allegations of irrelevance and confidentiality."

[2] In fact, the subpoena recipients have been cooperating with the United States. Prior to the filing of the motions to quash by Abbott and the Abbott-related entities, some of the third parties had already produced documents responsive to the subpoena and others were in the process of searching for and producing responsive documents. Since the filing of the motions to quash, the Government's third party discovery efforts have been severely interrupted.

discovery should include transaction data on other drugs sufficient to calculate the spreads, if any, on Abbott's other drugs, and general price setting and marketing. Moreover, the United States' should be permitted broader discovery into Abbott's corporate scienter, including but not limited to discovery of any Abbott division, segment or related entity regarding the pricing of its drugs, spreads, and any materials regarding third-party reimbursement for its drugs.

3. The United States should be allowed discovery beyond 1991 through 2003 to the extent it relates to how Abbott created list prices, AWP, marketed the spread, or the third-party reimbursement for any Abbott drug.

IV. STATEMENT OF FACTS

The United States has sued Abbott for creating enormous spreads on five of its products. Some of the spreads exceed 1,700%, with the smallest spread exceeding 200%. Abbott created "mega-spreads" on half of the NDC's named in the United States' Amended Complaint and almost all of the spreads exceed 500%.

The United States issued ten subpoenas to Abbott customers (the "Customer Subpoenas") on March 30, 2007. The United States issued three subpoenas to industry trade groups (the "Trade Group Subpoenas") on April 27, 2007 and one on May 11, 2007.

The Customer Subpoenas sought 13 categories of documents generally relating to the marketing and purchase of the drugs at issue in this case, the business that the third parties conducted with Abbott, along with related communications and analyses of purchase prices and spreads. TAP is never mentioned in the Customer Subpoenas. A sample Customer subpoena is attached hereto as Exhibit B.

The Trade Group Subpoenas sought 20 categories of documents generally relating to the membership of Abbott in the trade group, communications with the price reporting publications and government officials, and analyses of drug reimbursement policy and spreads. TAP is never mentioned in the Trade Group Subpoenas. A sample Trade Group subpoena is attached hereto as Exhibit C.

After the service of the subpoenas, the United States embarked upon a continuous and

extensive course of negotiations and discussions with many of the subpoena recipients relating to the scope of the subpoenas and the third parties' responses. In fact, prior to the filing of Abbott's, Hospira's and TAP's belated motions to quash, many of the third party subpoena recipients had already produced or were in the process of producing documents responsive to the United States's subpoenas, consistent with the parameters agreed to during discussions with the United States. Other subpoena recipients simply collected the documents and transmitted them to the United States without discussion. Abbott's untimely objections have interrupted this process.

V. THE MOTIONS TO QUASH

After the return dates had passed on 13 of the 14 subpoenas, Abbott, Hospira and TAP belatedly filed motions to quash. Hospira is a corporate spinoff of the division that manufactured the drugs that are identified in the United States' Amended Complaint. TAP is a joint venture in which Abbott was and is directly involved. In brief, all three Abbott-related entities moved to quash the subpoenas on largely the same grounds; because the subpoenas sought discovery on other drugs, other drug companies or events after 2003. The Abbott entities claimed that this discovery was so burdensome or so irrelevant as to not even be appropriate for discovery. Notably, none of the subpoena recipients objected to the subpoenas or joined in the Abbott entities' motion to quash. Nonetheless, the motions were granted on the basis of burden and relevance.

VI. CURRENT PARAMETERS OF DISCOVERY

The Order limits the discovery which can be pursued by the United States to the following:

(1) all documents that mention the four charged drugs;[3]

(2) all documents that relate to the four charged drugs including general sales, across the board marketing information that would encompass the four charged drugs, documents involving how Abbott "put together the spread" and cross cutting sales documents;

(3) all documents that reflect any alleged effort on the part of Abbott to market the spread or manipulate the published AWP for any drug within Abbott's former hospital products division; and

(4) the time period is limited to the end of 2003.

These discovery limits have impeded the United States' discovery efforts. The first sub-paragraph of the Order (the "subject drug" paragraph) states that discovery may include "all documents that mention the four charged drugs" (emphasis added). This sub-paragraph has been interpreted to mean that the United States is precluded from securing any discovery regarding "non-subject" drugs except in very narrow circumstances. In this regard, as is discussed *infra*, this sub-paragraph is too restrictive.

The second sub-paragraph of the Order (the "cross-cutting" paragraph) identifies the cross-cutting issues upon which the United States may obtain discovery of Abbott's other drugs and divisions. The number of cross-cutting issues, however, is broader than specified in this sub-paragraph, thereby making this sub-paragraph too restrictive.

The third key sub-paragraph of the Order (the "spread" paragraph) limits the United States' discovery to documents that reflect any effort to manipulate AWP or market the spread in just one division of Abbott. This limit is extremely prejudicial. Read literally, it prevents the United States from obtaining pattern and practice evidence regarding other Abbott divisions and

---

[3] On June 4, 2007, two days before the filing by Abbott, Hospira and TAP of motions to quash the United States' third-party subpoenas, the United States filed a Notice of Filing of the United States' First Amended Complaint, and the United States' First Amended Complaint, which, among other things, added the drug Acyclovir. Accordingly, the United States respectfully requests that any references to "charged drugs" in the Order, include the drug Acyclovir.

related companies. Further, this limitation accords Abbott or the producing party unilateral control over the production of documents that, in its view, show the marketing of the spread or AWP manipulation.[4] This provision also precludes the United States from conducting any discovery into the manner in which Abbott marketed its drugs or set prices in circumstances where AWPs and spreads were *not* in play.

The final key sub-paragraph (the "temporal" paragraph) of the Order limits discovery conducted by the United States to the end of 2003. Discovery prior to 1991 has generally been precluded as well. However, not all documents relating to the conduct at issue were necessarily generated during the period in which the actual false claims were submitted. This temporal scope limitation blocks the production of such evidence.

VII. ARGUMENT

The movant seeking to quash the subpoena has the burden of demonstrating undue burden to them or the third party; this requires the movant to provide affirmative proof of such burden through affidavits or record evidence. *In re Sulfuric Acid Antitrust Litigation*, 231 F.R.D. 351, (N.D. Ill. 2005); *Wagner v. Dryvit Systems, Inc.*, 208 F.R.D. 606, 610 (D. Neb. 2001); *Cliffstar Corp. v. Sunsweet Growers, Inc.*, 2003 WL 22350642 (W.D.N.Y. 2003) (a burdensomeness objection must be supported by an affidavit explaining in reasonable detail the factual basis for such an objection.); *Tequila Centinela, S.A. de C.V. v. Bacardi & Co. Ltd.*, 242 F.R.D. 1 (D.D.C. 2007) (objecting party must submit affidavits or evidence which reveals the nature of the burden). The objecting party also must show that the burden or expense is

---

[4] In the course of discovery to date, Abbott has already claimed that all of its lobbying related documents were irrelevant and refused to produce any such documents until ordered to do so by the Court. Yet these documents have shown that Abbott viewed Medicare reimbursement policies as "a marketing tool" and documented Abbott's efforts to eliminate a provision in a bill that required an audit by HHS because "that would get them looking at prices." These documents make it evident why Abbott should not be charged with evaluating relevance or AWP manipulation.

unreasonable in light of the benefits to be secured from the discovery. *Heartland Surgical Specialty Hospital, LLC v. Midwest Division, Inc.*, 2007 WL 950282, page 22 (D. Kan. 2007).

In sum, the proper procedure is to determine whether discovery is relevant or may lead to admissible evidence. Fed. R. Civ. P. 26(b)(1). A discovery request that is relevant on its face is enforceable unless such discovery would impose an undue burden; the movant must establish that burden. Fed. R. Civ. R. 26(b)(2). Abbott, Hospira and TAP have failed to establish such a burden here.

A. Certain Evidence Concerning Drugs Other Than Those Identified in the Amended Complaint is Directly Relevant to the Claims of the United States

The first three sub-paragraphs of the Order are focused on the same general issue; the extent to which the United States may take discovery concerning drugs not named in the Complaint – discovery it deems pertinent to establishing, for example, broader corporate scienter, motives and pattern and practice evidence. Unfortunately, the language of the Order's first three sub-paragraphs eliminates those and other relevant aspects of the discovery sought by the United States that are not drug-specific.

The Federal Rules of Civil Procedure were amended in 2000 to permit broader discovery than what is set forth in the Order. Rule 26(b)(1) permits discovery of any matter relevant to the *claim or defense* of any party as well as discovery reasonably calculated to lead to the discovery of admissible evidence. The 2000 Committee Notes explain that a variety of types of information not "directly" relevant to the claims in the suit could be relevant, including *"other incidents of the same type*, or involving the same product . . . ." The use of the term "or" shows that discovery is *not* limited to the exact same products. Accordingly, discovery is permitted into incidents of the same type of products that are at issue in a lawsuit and not just the specific products identified in the complaint. As discussed below, the United States does not seek all documents relating to all Abbott drugs and divisions; rather it seeks broader discretion to seek

discovery of conduct that bears on the issues in this case, even if the discovery crosses into other Abbott drugs and divisions.

Evidence regarding Abbott drugs not identified in the Amended Complaint is directly relevant to the claims of the United States *and* to the defenses asserted by Abbott. General evidence about other drugs is relevant because the United States is entitled to discover whether or not Abbott engaged in similar conduct with respect to its other products. In fact, the Court has recognized already that evidence regarding other drugs can be quite relevant for proving up the claims of the United States, specifically identifying "cross-cutting" marketing materials and AWP/spread documents.

Such evidence will be very persuasive. For example, whether or not Abbott had spreads on other products or marketed the spreads on only certain drugs is relevant to the claims of the United States. That evidence can show motive, knowledge, intent, as well as pattern and practice, and can also be used for impeachment. The evidence is relevant regardless of whether a document specifically shows the presence or absence of spreads (*e.g.*, has a column that reads "spread").

Abbott has also asserted that the United States failed to act reasonably when it relied upon Abbott's inflated AWPs. It is an odd defense because it essentially concedes the falsity of Abbott's reported prices. Nevertheless, discovery on other Abbott products could – and likely will – reveal that spreads existed on only a small portion of Abbott's drugs. If so, such evidence would substantially undermine Abbott's defense and help demonstrate that the United States reasonably relied on *Abbott's* price representations.

In addition, discovery regarding Abbott's conduct with respect to other drugs is necessary to rebut other defenses asserted by Abbott. Abbott has claimed or implied that it never reported AWPs for use by compendia on any drug:

> ..... Abbott does not set the AWP. They [the government] keep trying to do that. They keep trying to put that on us. We're not going to be able to give them anybody at Abbott who set AWP because we don't set AWP. That is the pricing compendia.

MDL 1456 Hearing, June 19, 2007, page 46, lines 18-21.

Another example is found in connection with United States' Interrogatory 12, which asked Abbott to identify employees involved with reporting AWPs. Abbott refused to answer the interrogatory because it "suggests that Abbott determines and/or reports an AWP." *See* Abbott's Response to United States' First Set of Interrogatories, p. 12, attached as Exhibit D. Abbott's objection was not limited to the drugs in the Complaint. Abbott cannot be allowed to defend the case on the basis that it never reported AWPs on any drug but object to the discovery by the United States on this very issue.

The United States already knows of the existence of some evidence that contradicts Abbott's defenses. For example, the United States has obtained copies of several transmittals from Abbott to various publishing companies where it provided AWPs for publication on many different drugs:

a. Michael Heggie, Abbott's Reimbursement Manager, wrote an internal e-mail dated January 16, 1996, stating that he wanted to change the AWP for Calcijex. *"I have reported for the past several years the AWP for Calcijex to both Red Book and Blue Book/First Data Bank* . . . . The reason this is important is that dialysis clinics are paid by Medicare for Calcijex. The Medicare Intermediaries get their pricing from the published AWPs of the three reporting agencies. Medicare pays 80% of published AWP. *We purposely set the AWP to be about 125% of the published single case price.* All other HPD products are reported with an AWP of 120% of list" to make the customer whole for reimbursement." *See* attached Exhibit E.

b. Heggie wrote to Medispan on January 16, 1996, stating *"will you please change the AWP for the following two list numbers."* He then provided the exact AWPs that he wanted published for Calcijex and conceded that he was overriding Medispan's usual formula. *See* attached Exhibit F.

c. Heggie wrote to Medispan again on September 19,1997, and stated, "[W]ould you please adjust the price of our product Calcijex . . . . *The New AWP will be*

$1323.69 per case" and on a second version of Calcijex stated, *"[T]he New AWP will be $2419.83 per case*." *See* attached Exhibit G.

d. An unsigned letter on Abbott letterhead was sent to Red Book on March 31, 1998, enclosing a list of AWPs on 11 different products. including Abbott's Biaxin Oral Suspension, Gabitril Tablets and PCE. *See* attached Exhibit H.

e. Tena Brown, Abbott Renal Care, wrote to Red Book on April 21, 1998 and specified for Abbott's "new product ZEMPLAR" that *"[t]he AWP to be included in the May publication are [sic] as follows: . . . $2648.00 . . . $5296.00". See* attached Exhibit I.

f. Brown, also wrote to Red Book on January 3, 2000, stating, "[W]ould you please adjust the price of our product Calcijex . . . *The New AWP will be $1390.66 per case*" and on a second version of Calcijex states *"The New AWP will be $2452.02 per case*." *See* attached Exhibit J.

Similarly, the United States obtained the 1998 letter attached hereto as Exhibit H directly from Red Book. This document was never produced by Abbott. The letter was sent by Abbott to Red Book and specified the AWPs that Abbott wanted to be published for four drugs not included in the Amended Complaint. The United States attached the letter as an Exhibit to its response to Abbott's Motion to Quash. Not long thereafter, Abbott for the first time produced the document attached hereto as Exhibit K. Exhibit K is an identical form letter sent in 1995 which directed Red Book to publish specific AWPs on almost 100 drugs, including two dozen drugs sold by Ross Pharmaceutical Products, a division of Abbott. Exhibit H and Exhibit K are both from Abbott's Pharmaceutical Products Division ("PPD") and thus, would not have been discoverable under the current language of the Order. Without third party discovery on this issue, the United States' would not have known of this important evidence.

Abbott cannot be allowed to defend the case on the basis that it never reported, set or caused the publication of AWPs for any drugs at any time and deny any and all discovery into this issue unless it is on the exact drugs in the Complaint, particularly when there is evidence not being produced by Abbott that shows otherwise. Additional discovery of Abbott's role in providing AWPs to the compendia is appropriate regardless of the drug.

B. Discovery Should be Allowed as to All Abbott Divisions that Sell and Market Drugs

This Court has already indicated that the United States should be allowed to conduct corporate-wide discovery into "cross-cutting issues." As discovery progresses, the United States is learning that many key issues – including Abbott's consideration of and lobbying on government reimbursement policy for its drugs – was done cross-divisionally and involved individuals from across the company. While the Court identified some cross-cutting issues – *e.g.*, sales and marketing type documents – it is becoming clear that there are numerous other cross-cutting issues in this case. In particular, evidence regarding Abbott's scienter – *i.e.*, its knowledge, reckless disregard, or deliberate ignorance of the truth or falsity of any aspect of the drug pricing scheme it is accused of having engaged in – is not limited to any one division of the company. If an Abbott division that makes drugs[5] other than those identified in the Complaint has documents about AWP, spreads or third-party reimbursement for Abbott drugs, those documents are germane to the United States' case regardless of whether recovery is sought for those drugs.

C. There Are Materials Beyond 2003 and before 1991 That Are Directly Relevant to the Claims of the United States and to the Defenses of Abbott

Discovery is not limited to the time period alleged in the complaint. *U.S. v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349 (11th Cir. 2005), *cert. denied*, 127 S. Ct. 554 (U.S. 2006) (discovery in *qui tam* for Medicare fraud was not limited to the date range of plaintiff's employment); *Jat, Inc. v. National City Bank of the Midwest*, 2007 WL 1880389 (E.D. Mich. 2007) (Plaintiffs are entitled to discovery of data for some period of time pre-dating their

---

[5] Abbott has many divisions that do not make drugs, including divisions dedicated to spinal devices, vascular devices, point-of-care diagnostic tools, diagnostic tests for cancer, molecular diagnostics, in vitro diagnostics, immunodiagnostics, clinical chemistry, glucose monitoring systems and test strips, and animal health products. While Abbott might legitimately contend discovery into those divisions would not be relevant, any Abbott division that makes drugs should not be excluded from discovery.

allegations in their quest for comparative information). In fact, this Court has already ruled that discovery should go beyond the period of damages alleged by the United States. Thus, discovery has been allowed through 2003. However, the Court stated that 2003 was not necessarily a firm cutoff date. Rather, the Court recognized that the facts may lead to the need for broader discovery and mentioned 2003 as being "a reasonable cutoff *for the time being*." Hearing before the Honorable Patti Saris, February 27, 2007, page 18 line 25 to page 19 line 1, attached as Exhibit L.

Evidence of Abbott's conduct after 2001 and 2003 is relevant. The fact that damages are not alleged past 2001[6] at this time or that Medicare stopped relying on AWP after 2003 is not determinative of this issue. Indeed, many Medicaid programs continued to use AWP after 2003.

Further, the various letters quoted above show that Abbott was quite willing to report AWPs for certain of its drugs in at least some circumstances prior to 2003. Year after year, from at least 1995 through at least 2000, Abbott directed Red Book to publish specific AWPs on various products. Yet, in follow up to an e-mail chain starting back in 2003, on April 22, 2004, an Abbott employee sent an e-mail to Red Book declaring, "[W]e do not establish or provide AWP." *See* Exhibit M. That e-mail is in stark contrast to the several letters sent to Red Book which tell it what AWP to publish on several different drugs over the course of several years. Thus, the United States is entitled to conduct discovery into Abbott's corporate policy and any changes thereto regarding AWPs reported to Red Book to determine when, why and by whom the policy was changed.

---

[6] In addition, the damages relating to the Dey defendants and the Roxane Defendants extend past 2003. A single, consistent approach to the discovery requested from third parties may very well lessen the burden on them in complying with third party discovery requests. At a minimum, the United States should have the ability to work these issue out directly with the third parties and not have an ill-fitting solution forced upon it by Abbott.

D. Many Hospira Materials are Relevant to this Case

Hospira challenged the United States' third party subpoenas on the basis that Hospira is a separate company from Abbott and that is was not formed until after 2003. However, the United States has directly shown why discovery relating to Hospira is necessary in this case.

There are many potential Hospira documents that could be relevant. Hospira was a spinoff corporation of Abbott HPD, which sold the drugs and products that are the subject of this lawsuit. At the time of the spinoff in May 2004, Hospira simply assumed Abbott HPD's sales contracts for the sales of these drugs and continued to fulfill Abbott's obligations thereunder. Some of these existing contracts extended for years and spanned both the operative period of the case and the period after the Hospira spinoff.

For example, the document attached as Exhibit N is a chart of list price changes instituted by Hospira on May 1, 2004, its first day in existence. Hospira lowered the list price on two forms of its vancomycin, both named in the Amended Complaint, from $46.05 to $25.53 and from $148.90 to $50.93. The price of one vancomycin formulation was slashed by almost half and the other was reduced to just 35% of its Abbott price. Prices on other products were slashed by more than 90%. The Hospira employees who implemented these price reductions obviously planned the reductions while they were Abbott employees. A reasonable hypothesis would be that *Abbott* made a decision not to announce these lower list prices until after the spinoff. Discovery into this suspicious conduct is relevant to this case and should not be foreclosed just because it occurred after 2003 or because Abbott orchestrated a corporate spinoff.

In addition, to the extent that Hospira continued Abbott HPD's existing contracts in dealing with third parties, third parties may have Hospira related information that is germane to the facts and issues in this case concerning those former Abbott HPD relationships, or marketing and pricing practices. Critically, how Hospira dealt with those existing Abbott HPD contractual

arrangements and third parties after the spinoff could be highly significant in showing Hospira's subsequent remedial measures and/or changes to the assumed existing Abbott HPD long term contractual arrangements. The Government is entitled to third party documents to identify Abbott HPD's course of conduct with regard to course of dealings, marketing, pricing and sales, and any changes that may have resulted at the time of or after the spinoff.

Seeking information from third parties concerning Hospira is also important in view of Abbott's discovery failures to date.[7] Hospira took over Abbott's HPD office space. At the time that Hospira assumed occupancy of the Abbott HPD office space, most or all of Abbott HPD's records *were not relocated to an Abbott location.* Possession, custody and control of those historic Abbott HPD documents were also assumed by Hospira, including all or most of Abbott HPD's books, records and computer data concerning Abbott HPD's sales activities for the drugs at issue in the Amended Complaint. Despite the Government's long outstanding discovery requests, Abbott has not produced additional Abbott HPD documents maintained by Hospira or located it Hospira's offices, despite several requests by the United States that it do so.

According to the March 2007 testimony of Abbott's 30(b)(6) witness, Abbott was going to undertake a search at Hospira for Abbott HPD documents. Since that deposition, the Government has been given no information that Abbott has even bothered to undertake such a search. As a result, the Government is entitled to see if third parties have such documents, at a minimum, in view of Hospira's and Abbott's production failures to date.

---

[7] The Government agreed to dismiss Hospira from its original suit only after Abbott and Hospira agreed that Abbott, on Hospira's behalf, would produce relevant documents in Hospira's possession custody or control. No such production has taken place to date and it is impeding the Government's discovery initiatives in this case. *See* Exhibit O.

E. TAP

As this Court is well aware, TAP is a joint venture between Abbott and Takeda Pharmaceuticals, Inc. TAP documents about AWP price manipulation and government reimbursement for drugs, including marketing the spread, are highly relevant to the Government's case. Even the minimal TAP-related evidence Abbott has produced to date indicates that Abbott and TAP personnel worked closely on AWP/government reimbursement issues.

Notably, in 2001, TAP settled civil claims that related, in part, to AWP price manipulation. TAP ultimately settled the civil claims for over $585 million in September of 2001.[8] The United States is not in a position to rule out at this time that some of the conduct at issue in this case and the conduct at issue in the TAP case are unrelated or did not overlap. Discussions about the spread between and among Abbott personnel, especially at the corporate

---

[8] TAP was also indicted and entered into a criminal plea agreement and paid in excess of $290 million for, among other conduct, the marketing and sale of a TAP injectable product. Incident to that criminal plea, TAP agreed to a limited waiver of attorney-client privilege over its documents and agreed to cooperate with the Government in the Government's investigation of others concerning the conduct, including price manipulation, at issue in the TAP case. TAP's criminal plea agreement included the following:

> "TAP agrees to cooperate completely and truthfully with the U.S. Attorney in connection with his on-going investigation and prosecution of others for alleged violations of federal criminal law arising out of his investigation. TAP understands and agrees that such cooperation shall include the following, if requested by the U.S. Attorney: . . .
>
> (a) prompt production to the U.S. Attorney of any document or record in the possession, custody or control of TAP relating to the subject matter of the investigation."

TAP also entered into a Corporate Integrity Agreement with the United States Department of Health and Human Services Office of Inspector General ("CIA"). Abbott similarly signed a letter agreement with the United States with regard to the TAP civil claims, agreeing to cooperate with the Government's investigations in September 2001. Despite these agreements, TAP and Abbott have actively impeded the United States' ability to investigate similar conduct at the related companies.

level, were not limited to one division, and in fact, was the same conduct at issue in the Governments' investigation into TAP. Further, some of the same individuals who were involved in or referenced in the TAP matter, including those responsible for government compliance, may also be involved in this case.

By way of example, in evaluating proposed Medicare and Medicaid policy and rule changes, Virginia Tobiason, who routinely worked with outside third parties including trade groups, included some suggestions relating to Abbott HPD, as well as *TAP*, and Abbott's Renal division, in a memo she wrote discussing the proposed Medicare AWP injectables pricing policy changes. (*See* Exhibit 757 to Deposition of Virginia Tobiason, attached hereto as Exhibit P). This memo was directed to senior officials at Abbott.

This memorandum is not an aberration; TAP was a "Key Participant" in Abbott's "Medicare Working Group." The Medicare Working Group dealt with Medicare-related issues and helped shape Abbott policy on Medicare reforms, including issues related to the government AWP-based reimbursement of drugs. *See* "Medicare Working Group Key Participants" and Minutes of March 6, 1997 and April 17, 1997 Medicare Working Group meetings, attached hereto as Exhibit Q.

Further, Abbott was heavily involved in lobbying on TAP's behalf to make sure that the way Lupron was reimbursed was advantageous. For example, the Abbott Divisional Vice-President in charge of lobbying issued routine reports documenting Abbott's efforts on behalf of TAP. The reports noted that he had a "*meeting with TAP staff and staff of Senator Roth (R-DE), Chairman of the Senate Finance Committee, to discuss HCFA's current reimbursement policy for Lupron.*" Another report from the same Abbott Divisional Vice-President noted that he had held *"a conference call with TAP and a Washington consultant on HCFA possibly looking into lowering Lupron's reimbursement rate.*" *See* documents attached hereto as Exhibit R. Although

the United States finally got these few documents, the scope of Abbott's role in the spread marketing activity and manipulation of government reimbursement for drugs at TAP has never been fully explored. Abbott's efforts to keep the government from lowering AWP-based reimbursement for TAP's drug Lupron is quite relevant in this case regardless of the drug, or the fact that it was sold in the United States by an Abbott joint venture.

F. Abbott, Hospira and TAP Completely Failed to Show Any Burden

None of the moving parties were being asked to produce a single document and therefore never demonstrated any burden whatsoever. Abbott included a section in its Motion to Quash which discusses whether the burden of reviewing discovery obtained from third parties should be a factor in this matter. However, a close reading of the motion demonstrates that Abbott never actually states that reviewing these documents would be a burden and certainly never asserts that reviewing the documents would be an *undue* burden. And, of course, there is no evidentiary support in Abbott's motion for granting its requested relief based upon a claim of burden, let alone upon an unsupported claim of burden.

VIII. THE TRADE GROUP SUBPOENAS

In addition to the other issues raised herein, the United States additionally notes that there should be no "charged drug" limit on the Trade Group subpoenas. The trade groups are not in the business of buying and selling drugs. They advocate regarding government drug reimbursement issues on a general basis. Thus, the underlying basis for limiting discovery to the charged drugs is inapplicable. As noted, the Trade Group subpoenas generally seek communications with the price reporting publications and government officials, and analyses of drug reimbursement policy and spreads. Limiting the Trade Group subpoenas to those documents mentioning the charged drugs would eliminate wide swaths of relevant documents pertaining to general policy and communications regarding Medicare and Medicaid drug

reimbursement.

IX. CONCLUSION

Wherefore, the United States respectfully requests that its objections be sustained, that the scope of discovery be revised in accordance with the relief requested in Section III of this pleading, and that the Court grant such other and further relief as the Court deems just and proper.

Respectfully submitted,

For the United States of America,

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY

George B. Henderson, II
Assistant U.S. Attorney
John Joseph Moakley
U.S. Courthouse
Suite 9200, 1 Courthouse Way
Boston, MA 02210
Phone: (617) 748-3272
Fax: (617) 748-3971

R. ALEXANDER ACOSTA
UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF
FLORIDA

/s/ Mark A. Lavine
Mark A. Lavine
Ana Maria Martinez
Ann St. Peter-Griffith
Special Attorneys for the Attorney
General
99 N.E. 4th Street, 3rd Floor
Miami, FL 33132
Phone: (305) 961-9003
Fax: (305) 536-4101

PETER D. KEISLER
ASSISTANT ATTORNEY GENERAL

/s/ Rebecca A. Ford
Joyce R. Branda
Daniel R. Anderson
Renée Brooker
Justin Draycott
Rebecca A. Ford
Gejaa T. Gobena
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
Phone: (202) 307-1088
Fax: (202) 307-3852

For the relator, Ven-A-Care of the Florida
Keys, Inc.,

James J. Breen
The Breen Law Firm, P.A.
3350 S.W. 148th Avenue
Suite 110
Miramar, FL 33027
Phone: (954) 874-1635
Fax: (954) 874-1705
Email: jbreen@breenlaw.com

Dated: August 15, 2007

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above **UNITED STATES' OBJECTIONS TO JULY 19, 2007 ORDER BY MAGISTRATE JUDGE BOWLER** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Rebecca A. Ford
Rebecca A. Ford

Dated: August 15, 2007